UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,683	08/28/2003	Imants Lauks	PAT 927-2 US	5656

26123 7590 01/07/2009

BORDEN LADNER GERVAIS LLP
Anne Kinsman
WORLD EXCHANGE PLAZA
100 QUEEN STREET SUITE 1100
OTTAWA, ON K1P 1J9
CANADA

EXAMINER	
NAGPAUL, JYOTI	
ART UNIT	PAPER NUMBER
1797	

NOTIFICATION DATE	DELIVERY MODE
01/07/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipinfo@blgcanada.com
aarmstrongbaker@blgcanada.com
akinsman@blgcanada.com

Office Action Summary	Application No.	Applicant(s)	
	10/649,683	LAUKS ET AL.	
	Examiner	Art Unit	
	JYOTI NAGPAUL	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,14-28 and 81-85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12, 14-28 and 81-85* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment filed on October 22, 2008 has been acknowledged. Claims 1-12, 14-28 and 81-85 are pending.

Response to Amendment

Rejection of Claims 1-9, 13-14, 21, 24-28, 81, 83 and 84 as being anticipated by Stiene (WO 02/49507) has been modified in light applicants' amendments and remarks.

Rejection of Claims 10-12, 15-20, 22-23 and 82 as being unpatentable over Stiene in view of Paul (US 6013164) has been modified in light applicants' amendments and remarks.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1-9, 13-14, 21, 24-28, 81, 83 and 84** are rejected under 35 U.S.C. 102(b) as being anticipated by Stiene (WO 02/49507).

As for Claims 1-9, Stiene teaches an apparatus for measuring certain properties of a fluid. The apparatus comprises an integral injector fluid reservoir/penetration device/ lancing system (4) for containing the aqueous injector fluid, an initially dry microporous lateral flow strip (115) (See pg 34, Lines 3-10) having a fluid application end (7) for accepting injector fluid and an effluent end, for example the location where the fluid stops where the vent (81) is in Figure 8i, for delivering to the receiving location,

see Figure 6e. Sitene further teaches a valve which is included in a control unit or meter device (See pg 28, Lines 1-7) for fluidically connecting the reservoir with the fluid application end to supply the injector fluid to the application end. Stiene further teaches an isolator/vent/air gap (81) for fluidicly isolating the effluent end from the receiving location when the fluidic path includes a fluid. Stiene further teaches driving means/pair of electrodes (610) for osmotically pumping injector fluid out of the effluent end of the fluidic path element and across the isolator to the fluid receiving location of a downstream device. (See Figures 6c-6e) Stiene further teaches a sealing element/laminate for sealing the fluidic path along a perimeter thereof to prevent fluid flow from the fluidic path/channel at the perimeter during electro-osmotic pumping. (For example, see pg 27, Lines 13-18 and pg 29 Lines 25-34) With respect to Claim 14, Stiene's device is clearly capable of generating a field free region in the fluidic path at the effluent end during electro-osmotic pumping.

As for Claim 21, Stiene fails to teach the electro-osmotically pumped fluid has an electrolyte concentration of less than 10 milimolar. However, applicants' are claiming an apparatus. It is fundamental that an apparatus claim defines the structure of the invention and not how the structure is used in a process or what ***material*** the structure houses in carrying out the process. (See Ex parte Masham) As long as the device of Stiene is capable of electro-osmotically pumping fluid that has an electrolyte concentration of less than 10 milimolar, then the prior art meets the requirements of the claimed feature.

As for Claims 81 and 84, Stiene teaches an apparatus for measuring certain properties of a fluid. The apparatus comprises an initially dry fluidic path (4) having a fluid application end (7) for accepting injector fluid and an effluent end, for example the location where the fluid stops where the hydrophobic gate is in Figure 6c, for delivering to the receiving location, see Figure 6e. Stiene further teaches an isolator/hydrophobic gate for fluidicly isolating the effluent end from the receiving location when the fluidic path includes a fluid. Stiene further teaches driving means/electrodes for osmotically pumping injector fluid out of the effluent end of the fluidic path element and across the isolator to the fluid receiving location of a downstream device. (See Figures 6c-6e) Stiene further teaches a sealing element/laminate for sealing the fluidic path along a perimeter thereof to prevent fluid flow from the fluidic path/channel at the perimeter during electro-osmotic pumping. (For example, see pg 27, Lines 13-18 and pg 29 Lines 25-34)

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. **Claims 10-12, 15-20, 22-23 and 82** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stiene in view of Paul (US 6013164).

Refer above for the teachings of Stiene.

Paul teaches an apparatus for pumping and manipulating fluid flow in packed capillary based systems. Paul discloses at least one capillary channel forming a fluid passageway and having a porous dielectric medium disposed therein to cause an electrolyte to move in the microchannel and increase fluid flow control through the system. (See Col. 1, Lines 58-68) (See Col. 2, Lines 1-10)

As for claims 10-11 and 15-16, Stiene fails to teach the fluidic path contains a mobilizable reagent selected from the group of luminogenic, flurogenic, electrogenic and chemolumiescent substrates and combinations thereof. However, applicants' are claiming an apparatus. It is fundamental that an apparatus claim defines the structure of

the invention and not how the structure is used in a process or what material the structure houses in carrying out the process. (See Ex parte Masham) As long as the fluidic path of Stiene and Paul are capable of containing a mobilizable reagent, the prior art meets the requirements of the claimed feature.

Additionally, it would have been obvious to one having ordinary skill in the art to provide the fluidic path of Paul with a mobilizable reagent selected from the group of luminogenic, flurogenic, electrogenic and chemolumiescent substrates and combinations thereof to achieve the predictable results of versatility in detection of the sample.

As for claim 17-18, Stiene fails to teach an integral fluid reservoir. It would have been obvious to one having ordinary skill in the art to provide an integral fluid reservoir with sample or fluid to achieve the predictable results of maximizing the efficiency of the device.

As for claims 19 and 20, Stiene and Paul fails to teach the micro-porous fluidic path has pores less than 0.2 micrometer radius. Paul teaches micro-porous fluidic path. It would have been obvious to one having ordinary skill in the art to provide the device of Stiene and Paul with a micro-porous fluidic path having pores less than 0.2 micrometer radius to achieve the predictable results of obtaining the analyte of interest and thus increasing the efficiency of the overall process.

As for Claims 22 and 23, Stiene and Paul fail to teach the fluidic path is trapezoidal shaped with its fluid application end wider than its effluent end. It would have been obvious to one having ordinary skill in the art to provide a fluidic path that is

trapezoidal shaped with its fluid application end wider than its effluent end to achieve predictable results of better flow control through the device.

Response to Arguments

7. Applicant's arguments filed on October 22, 2008 have been fully considered but they are not persuasive. Applicants' argue that Steine does not disclose nor suggest a pump including an integral injection fluid filled reservoir and a valve for selecting releasing the fluid from the reservoir. Examiner respectfully disagrees. Steine does teach an integral injection fluid reservoir (4) and a valve that is included in the control unit or meter. Applicants' further argue that Steine does not teach the reservoir is integral to the pump. Examiner respectfully disagrees. Applicants' recite in the preamble of the claim to define this. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTI NAGPAUL whose telephone number is (571)272-1273. The examiner can normally be reached on Monday thru Friday (10:00-7:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JN

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797